Posterior Arch Augmentation (Spinoplasty) before and after Single and Double Interspinous Spacer Introduction at the Same Level: Preventing and Treating the Failure?

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Summary

Lumbar spinal canal stenosis (LSCS) is one of the most common degenerative diseases in elderly patients. Failure of he treatment can occur, generally related to bone remodelling/fracture of spinous processes. PMMA augmentation of the posterior arch (spinoplasty, SP) has recently been proposed in case of neoplastic involvement. This study evaluated the efficacy of SP as a prophylactic treatment before introducing an interspinous spacer (IS). Moreover, we consider the possibility to treat patients who previously underwent IS implants with subsequent failure of the device, by introducing a second spacer at the same level, performing accessory SP. From January 2009 to September 2011, 174 patients with LSCS underwent CT-guided percutaneous IS implant in our department. From January 2011, all patients with osteoporosis underwent prophylactic SP before introducing the spacer. Moreover, in patients with re-stenosis related to bone remodelling and/or fracture, after strengthening the spinous processes with PMMA introduction, a second similar device was introduced to re-open the stenotic spinal canal. In patients with prophylactic treatment before spacer introduction, no restenosis occurred at three to 12 month follow-up. Patients who underwent second spacer implant at the same level after posterior arch augmentation again obtained a resolution of symptoms, and no further bone remodelling had occurred at follow-up controls. In conclusion, prophylactic SP prevents single spacer failure for bone remodelling/fracture, and allows failure repair by introducing a second spacer at the same level.

Introduction

Lumbar spinal canal stenosis (LSCS) is one of the most common degenerative diseases in elderly patients, generally responsible for neurogenic claudication, numbness and weakness to the lower limbs, finally leading to paraparesis ¹. Chronic radicular nerve ischaemia secondary to radicular vein compression related to spinal canal and/or foraminal stenosis is generally advocated as the cause of the symptoms, and posterior arch distraction frequently offers a solution to the disease, according to several biomechanical studies ²⁻³.

Although conventional surgical decompression is considered the final solution for the treatment of LSCS, percutaneous interspinous spacers (IS) have recently been proposed to obtain distraction of the spinous processes, reducing compression from interspinous ligaments, arresting the progressive syndrome and reducing lower limb radiculopathy 4,5. Moreover, the indication for IS implants has recently been extended to lumbar discogenic pain, facet joint syndromes, disc herniation and low-grade instability 6. Unfortunately, 7% to 13% of patients treated with IS experience an early recurrence

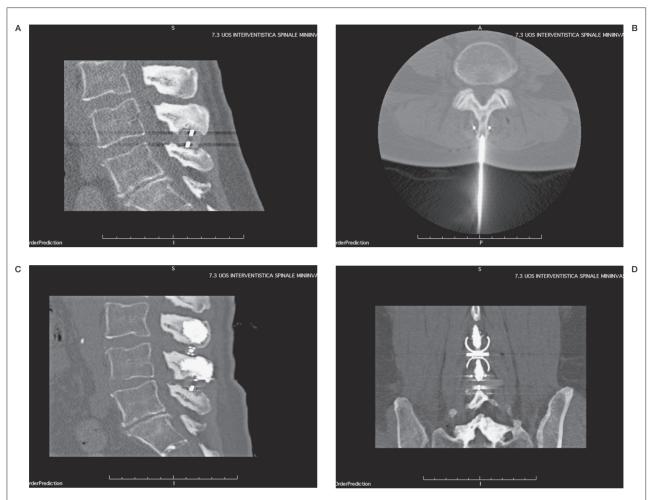


Figure 1 Prophylactic spinoplasty in a Group A patient with spinal canal stenosis at L3/L4 level, and previous introduction of a spacer at L4/L5 level. Before surgery, the former spacer (Helifix® type, fully Peek, no wings) can be appreciated at L4/L5 level (A), with mild spinous process bone remodelling. A new spinal canal stenosis at L3/L4 level responsible for recurrence of symptoms was appreciated on MR scan (not shown). Augmentation of the posterior arch was performed by introducing a Jamshidi needle into the spinal processes at L3 and L4 level (B) and after PMMA injection, a new device (InSpace®, fully Peek, bilateral metallic wings) was introduced at L3/L4 level (C,D).

of symptoms because of posterior laminae fracture and/or remodelling, generally related to focal bone tenderness (i.e., osteoporotic disease and/or excessive stress overload), reducing the formerly obtained distraction, even in patients treated with new soft non-metallic polyetheretherketone (PEEK) devices 7. Vertebroplasty is widely accepted as the choice technique in strengthening vertebral bone and recently several applications besides the vertebral bodies (i.e. sacral fracture, posterior arch tumoral involvement) have been proposed 8-11. This study evaluated the possibility to prevent bone remodelling of the laminae in osteoporotic patients scheduled for IS implants by obtaining pre-operative posterior arch augmentation (spinoplasty, SP) using prophylactic percutaneous CT-guided PMMA injection into the posterior arch. Moreover, we considered the possibility to treat patients who previously received conventional IS implants with subsequent failure of the device, by performing local SP and introducing a second IS device at the same level, anteriorly or posteriorly to the former implant. To our knowledge, no report on prophylactic SP and double IS implants at the same level has been published.

Material and Methods

From January 2009 to September 2011, 174 patients with LSCS underwent CT-guided percutaneous IS implant in our department. The

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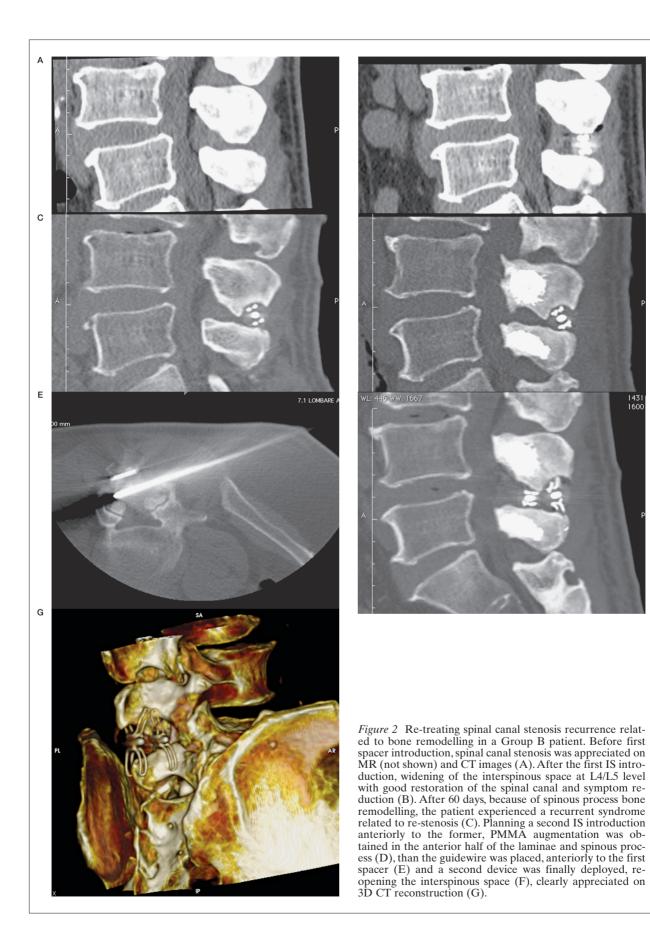




Figure 3 After IS introduction, increased disc vacuum can be frequently appreciated at the level of surgery, generated by disc decompression related to interspinous space distraction.

age of patients ranged from 56 to 82 years old (mean age was 72 years): among them, 148 patients suffered from symptoms related to spinal canal stenosis (three cases at L2/L3 level, 30 cases at L3/L4 level, 111 at L4/L5 level, and two cases with L3/L4 and L4/L5 levels), while 26 had severe local foraminal stenosis (seven cases with unilateral, 19 with bilateral stenosis) related to LSCS and grade I spondylolisthesis (14 patients) with or without (12 patients) disc degeneration.

All patients underwent clinical evaluation and quality of life and self-rated pain were assessed using the visual analogue scale (VAS). Pre-operative mean value of the VAS scale was 8.2. Moreover, pre-operative EMG evaluation of the inferior limbs and a lumbar CT-MR study were performed.

We used two different kinds of PEEK-coated IS devices, with a pair of metallic wings for spinous process encasement (In-Space®, Synthes-DePuy, Switzerland), or fully PEEK spiral body without external wings (Helifix®, Alphatec, CA, USA). The IS size ranged from 8mm to 14mm (two patients were treated with 8mm devices, 52 with 10 mm, 116 with 12 mm and four with 14 mm), and the patients had a single level treated, while a double-level treatment was performed only in two cases. The treatment was performed under local anaesthesia with analgosedation 12 directly in a CT suite, using CT scans to introduce the K-wire in the selected interspinous space using a posterolateral approach, with a small 5-10 mm skin incision. A C-arm mounted on the CT-cradle was used as a radiological guide for the introduction of progressive dilatators (from 8 mm to 14 mm depending on the case) and final application of the IS device was performed under fluoroscopic guidance. Total working time was approximately 30 to 45 minute.

To avoid IS treatment failure related to osteoporosis, starting from January 2011 all candidates for IS implants underwent bone mineral density scan (BMD) to disclose any osteoporotic disease, and in 45/174 patients (26% - Group A), because of their severe osteoporotic condition, prophylactic posterior laminae augmentation with PMMA was performed before IS implants. All patients returned for one, three and 12 month follow-up clinical evaluation.

In 18/174 patients treated before January 2011 (11% - Group B), after a disappearance of original symptoms at one-month follow-up (VAS mean value was 1.5), a return of original symptoms was referred, the VAS scale rising back to 7.4 in one to 12 months (mean three months). All the patients with recurrent symptoms underwent a new CT study (spiral CT, 1mm thickness, sagittal 2D recons, mA rate was lowered to a minimum value of 20 mA), demonstrating spinous process bone remodelling, encasing the IS and restoring the original stenosis.

In Group A patients, posterior arch augmentation was performed using a CT guide and C-arm technique, introducing a 13G needle inside the spinous processes on sagittal orientation (36 patients) or parasagittal oblique route (nine patients), and 1-2 cc of PMMA were injected into the laminae. The IS device was introduced immediately after, according to the technique described above.

Fifteen out of 18 Group B patients, who experienced failure of the previous IS treatment because of bone remodelling, were offered prophylactic SP treatment and implantation of a

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second IS device at the same level as the previous one, in an attempt to raise the interspinous space back again. All patients underwent SP treatment according to the method described above and particular attention was paid to the selected area of PMMA deposition (immediately above and below the chosen site for the second implant). Then, the second IS device was introduced, in three cases posteriorly to the former, and in 12 cases anteriorly (Figure 1), according to the space available as shown by pre-operative 2D CT reconstruction. Follow-up CT study was than performed at one, three and 12 months, according to the adopted protocol.

Results

None of the patients in Group A, who underwent prophylactic SP had complications related to PMMA injection, and no extra-laminar leakage was detected except in one patient who had no symptoms related to the minimal paraspinous leakage. No symptom recurrence related to the LSCS was referred at the follow-up control after three to 12 months, and VAS scale mean value was lowered to 2.

CT control studies demonstrated optimal persistent distraction of the interspinous space and foramina at the treated level, with no posterior arch remodelling thanks to the PMMA augmentation (Figure 2), even at the last one year follow-up control.

In the 15 patients treated with a double IS device at the same level (Group B), the recurrent symptoms referred after the failure of the first IS implant completely resolved after the second treatment (prophylactic PS + IS treatment), and they remained painless at the follow-up control at one to 12 months. No other symptoms were referred in patients with a double IS implant.

Discussion

Biomechanical studies stress the concept of "dynamic stabilization" of the posterior arch, avoiding posterior fusion: the apposition of IS reduces discal load (Figure 3) avoiding local anterior spinal column stress ¹³⁻¹⁴, suiting the up-to-date idea of "functional spinal unit".

Although posterior stabilization and fixation using conventional open-surgery has been performed for several years, there has recently been increasing interest in developing percutaneous stabilization systems. Fully percutaneous treatments have the great advantage of reducing surgical time, post-operative recovery time, and do not need general anaesthesia, being well tolerated and accepted by the patient.

The oldest fully titanium made devices have recently been replaced by PEEK-coated IS, to minimize mechanical stress between the posterior arch bone and the device itself. Nevertheless, failure of the procedure related to posterior laminae remodelling and restoration of the original stenosis can occur even in this case.

Pedicle and transverse process augmentation has been described 15, with pain resolution in case of neoplastic involvement, and no complications were reported. The vertebral posterior arch can easily be strengthened by PMMA injection by introducing a 13 to 15G needle into the spine processes along the midline or adopting a parasagittal oblique approach, reaching the crus of the laminae directly 8. A small amount of PMMA (generally 1 to 3cc) introduced under fluoroscopic guidance is easy to perform and the PMMA remains inside the spongy bone because of the thick cortex of the laminae. By adopting prophylactic SP, the treatment with IS placement was durable in our patients, with no risk of recurrent syndrome even after one-year follow-up study. Introducing a IS after SP does not require a different approach or precautions.

To date, when a spacer failure occurs because of spinous process remodelling and/or fracture, more aggressive open surgery is considered the only solution to decompress the spinal canal again. However, surgical decompression generally includes bilateral laminectomy and posterior interbody fusion (PIF) using screws and rods in general anaesthesia. Complications related to scars and/or osteoporosis have been described with a conventional surgical approach ¹⁶⁻¹⁸. For this reason, re-treatment with local anaesthesia should be preferred, particularly in elderly patients.

In our patients with a failure of previously inserted IS, we managed to obtain resolution of the recurrent LSCS by introduction of a second device at the same level, the spinous process being protected by prophylactic posterior arch augmentation. Although the introduction of a second IS device at the same level has not been described, the technique seems to be easy to perform in patients with failure of previous

IS implants and sufficient space in front or behind the former spacer. When sufficient distraction is achieved thanks to the insertion of the second device, the clinical symptoms are significantly reduced or disappear completely, the central spinal canal and/or foramina being newly decompressed.

Conclusion

Posterior arch augmentation seems to be a promising technique in preventing IS failure in patients with spinal canal stenosis undergoing percutaneous spacer insertion. It is an easy-to-perform technique to be adopted in all the patients at-risk for fracture or bone remodelling generated by osteoporosis or other bone stress conditions.

The failure of a previously implanted IS device related to bone remodelling/fracture in those patients who did not undergo prophylactic SP can be safely resolved with targeted SP and the introduction of a second IS device, restoring the distraction and reducing the recurrent clinical syndrome related to re-stenosis.

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